510(k) Summary

As required by 21 CFR 807.92(c)

OCT 18 2010

510(k) Number: K102721

Date Prepared: September 20, 2010

Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126 Establishment Registration Number: 3005188751
Contact Person:	Nicole Bowden Sr. Regulatory Affairs Specialist Tel: 651-756-5162 Fax: 952-930-9481 nbowden@sjm.com

Device Information:

Trade Name:	Livewire™ Electrophysiology Catheter
Common Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter
Class:	Class II, 21 CFR 870.1220, Product Code DRF

Predicate Device:

Livewire™ Electrophysiology Catheter (K022380 and K913940)

Device Description:

The SJM Livewire™ Steerable Electrophysiology Catheter is a flexible electrode catheter constructed of a polyurethane insulation/shaft and incorporates platinum electrodes. The active tip may be manipulated by remote means located at the proximal end of the catheter.

Indications for Use:

The St. Jude Medical (SJM) Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Comparison to Predicate Devices:

The modified Livewire™ Electrophysiology Catheters have the same intended use and fundamental scientific technology as the predicate devices. All technological characteristics of the modified Livewire™ Electrophysiology Catheters are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Through performance

testing it was demonstrated that the design modifications do not adversely affect the safety and effectiveness.

Summary of Non-Clinical Testing:

Bench testing of the modified Livewire™ Electrophysiology Catheters was performed to verify the device modifications. Results of the testing demonstrate that the modified Livewire™ Electrophysiology Catheters design meets the product specification and intended use.

Statement of Equivalence:

The modified St. Jude Medical Livewire™ Electrophysiology Catheters have the same indications for use and technological characteristics as the predicate devices. Based on this and the data provided in the pre-market notification, St. Jude Medical's modified Livewire™ Electrophysiology Catheters have been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2010

St. Jude Medical
c/o Nicole Bowden
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K102721
Trade/Device Name: Livewire Electrophysiology Catheters
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe.
Regulatory Class: Class II (two)
Product Code: DRF
Dated: September 20, 2010
Received: September 21, 2010

Dear Ms. Bowden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102721

INDICATIONS FOR USE

OCT 18 2010

510(K) Number (if known): K102721

Device Name: Livewire™ Electrophysiology Catheter

Indications for Use:

The St. Jude Medical (SJM) Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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